UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: TAXOTERE (DOCETAXEL) PRODUCTS LIABILITY LITIGATION	)	**MDL No. 16-2740**
	)	**SECTION: "H" (5)**
This document relates to: Elizabeth Kahn, 16-17039	)	

ORDER AND REASONS

Before the Court is Plaintiff's Motion to Exclude Testimony of Dr. Janet Arrowsmith (Doc. 10926). The Court held oral argument on the Motion on October 6, 2020. For the following reasons, the Motion is **DENIED**.

BACKGROUND

Plaintiffs in this multidistrict litigation ("MDL") are suing several pharmaceutical companies that manufactured and/or distributed a chemotherapy drug, Taxotere or docetaxel,[1] that Plaintiffs were administered for the treatment of breast cancer or other forms of cancer. Among these companies are Defendants sanofi-aventis U.S. LLC and Sanofi U.S. Services Inc. (collectively, "Sanofi" or "Defendants"). Plaintiffs allege that the drug caused permanent alopecia—in other words, permanent hair loss. Plaintiffs bring claims of failure to warn, negligent misrepresentation, fraudulent misrepresentation, and more. The first bellwether trial was held in September 2019, and the second trial is set for 2021.[2]

In the instant Motion, Plaintiff Elizabeth Kahn, the second bellwether plaintiff, moves to exclude testimony from Dr. Janet Arrowsmith. Dr. Arrowsmith is a doctor in internal medicine, an epidemiologist, and a former

[1] Docetaxel is the generic version of Taxotere.
[2] The second trial was continued due to the COVID-19 pandemic.

FDA employee. Plaintiff argues that Dr. Arrowsmith's opinions are unreliable and that she did not properly disclose her opinions. Sanofi opposes the Motion.

LEGAL STANDARD

The admissibility of expert testimony is governed by Federal Rule of Evidence 702, which provides as follows:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
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> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
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> (b) the testimony is based on sufficient facts or data;
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> (c) the testimony is the product of reliable principles and methods; and
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> (d) the expert has reliably applied the principles and methods to the facts of the case.[3]

The current version of Rule 702 reflects the Supreme Court's decisions in *Daubert v. Merrell Dow Pharms., Inc.*[4] and *Kumho Tire Co. v. Carmichael*.[5] The threshold inquiry in determining whether an individual may offer expert testimony under Rule 702 is whether the individual has the requisite qualifications.[6] After defining the permissible scope of the expert's testimony, a court next assesses whether the opinions are reliable and relevant.[7] As the

[3] FED. R. EVID. 702.
[4] 509 U.S. 579 (1993).
[5] 526 U.S. 137 (1999).
[6] Wagoner v. Exxon Mobil Corp., 813 F. Supp. 2d 771, 799 (E.D. La. 2011). *See also* Wilson v. Woods, 163 F.3d 935, 937 (5th Cir. 1999) ("A district court should refuse to allow an expert witness to testify if it finds that the witness is not qualified to testify in a particular field or on a given subject.").
[7] *See* United States v. Valencia, 600 F.3d 389, 424 (5th Cir. 2010). *See also* Wellogix, Inc. v. Accenture, L.L.P., 716 F.3d 867, 881–82 (5th Cir. 2013).

"gatekeeper" of expert testimony, the trial court enjoys broad discretion in determining admissibility.[8]

First, to assess reliability, a court considers whether the reasoning or methodology underlying the expert's testimony is valid.[9] The party offering the testimony bears the burden of establishing its reliability by a preponderance of the evidence.[10] Courts should exclude testimony based merely on subjective belief or unsupported speculation.[11] Courts must, however, give proper deference to the traditional adversary system and the role of the jury within that system.[12] "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."[13] After assessing reliability, a court evaluates relevance.[14] In doing so, a court must determine whether the expert's reasoning or methodology "fits" the facts of the case and will thereby assist the trier of fact in understanding the evidence.[15]

Federal Rule of Evidence 703 further provides that an expert may offer opinions based on otherwise inadmissible facts or data but only if (1) they are of the kind reasonably relied upon by experts in the particular field; and (2) the testimony's probative value substantially outweighs its prejudicial effect.[16]

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[8] *Wellogix*, 716 F.3d at 881.
[9] *See Daubert*, 509 U.S. at 592–93.
[10] *See* Moore v. Ashland Chem. Inc., 151 F.3d 269, 276 (5th Cir. 1998).
[11] *See Daubert*, 509 U.S. at 590.
[12] *See id.* at 596.
[13] *Id.*
[14] Burst v. Shell Oil Co., 120 F. Supp. 3d 547, 551 (E.D. La. June 9, 2015).
[15] *Id.*
[16] FED. R. EVID. 703.

LAW AND ANALYSIS

I. Dr. Arrowsmith's Opinions on Causation and TAX 316

Plaintiff first argues that Dr. Arrowsmith opines on other causes of persistent hair loss without using a reliable methodology to assess causation for these other possible causes. In response, Sanofi argues that unlike Plaintiff, Sanofi is not required to prove general causation and need not use the same methodologies as Plaintiff. Instead, Dr. Arrowsmith is only offering rebuttal evidence and challenging Plaintiff's "proof" that Taxotere is the sole cause of Plaintiff's permanent hair loss. According to Sanofi, Dr. Arrowsmith opines only that the currently available scientific evidence is insufficient to establish that Taxotere alone causes permanent alopecia, noting that the existing data is "too confounded to make such an assertion with any scientific or medical certainty,"[17] and consistent with this, she offers reasonable hypotheses about other drugs that are associated with persistent hair loss.

Plaintiff Kahn bears the burden of proving that Taxotere caused her injury, and she must prove both general and specific causation.[18] Defendants may then challenge her evidence with admissible evidence of other possible

[17] Doc. 10926-3 at 7.

[18] Seaman v. Seacor Marine LLC, 564 F. Supp. 2d 598, 600 (E.D. La. 2008), *aff'd*, 326 F. App'x 721 (5th Cir. 2009) ("[T]he plaintiff must present admissible expert testimony to establish general causation as well as specific causation."); Knight v. Kirby Inland Marine Inc., 482 F.3d 347, 351–52 (5th Cir. 2007) (assessing trial court plaintiffs' general causation evidence); Burst v. Shell Oil Co., Civil Action No. 14-109, 2015 WL 3755953, at *1 (E.D. La. June 16, 2015) ("[P]laintiff must show general causation—that gasoline containing benzene can cause AML—and specific causation—that defendants' products caused Mr. Burst's AML."); *Wagoner*, 813 F. Supp. 2d at 800 ("To prevail in a toxic tort case, a plaintiff must show both general causation and specific causation."); Frischhertz v. SmithKline Beecham Corp., Civil Action No. 10-2125, 2012 WL 6697124, at *6 (E.D. La. Dec. 21, 2012) (granting summary judgment because "plaintiffs have no expert testimony establishing general or specific causation and cannot meet their burden of establishing either general or specific causation from the ingestion of Paxil for the alleged birth defects under the [Louisiana Products Liability Act]").

causes.[19] As noted by the Fifth Circuit, to establish causation under the Louisiana Products Liability Act, a plaintiff using circumstantial evidence to prove causation must establish "with reasonable certainty that all other alternatives are impossible."[20] The burden is not on the defendant to prove that other causes are possible.[21] Plaintiff has not pointed to any law providing that a defendant must prove general causation before testifying about possible alternative causes of a plaintiff's injury, and this Court has found no such law. The Court, therefore, will not limit Dr. Arrowsmith's testimony because she did not use one of the methodologies associated with proving general causation.

Next, Plaintiff raises a specific challenge to a statement by Dr. Arrowsmith about the results of the TAX 316 study.[22] In her report, she states:

> With respect to "ongoing alopecia" there were 29 cases (4.2%) in the TAC arm and 16 (2.5%) in the FAC arm from the TAX 316 final clinical study report. These results do not constitute a signal of an increased risk for an association between TAC and "ongoing alopecia" as there is not a statistically significant difference between the incidence of "ongoing alopecia" in the two arms.[23]

Plaintiff argues that Dr. Arrowsmith fails to describe or identify any calculation supporting this statement. Indeed, Dr. Arrowsmith's report is lacking in this regard. However, in her deposition testimony, Dr. Arrowsmith

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[19] Wheat v, Pfizer, Inc., 31 F.3d 340, 342–43 (5th Cir. 1994). In *Wheat*, the Fifth Circuit wrote that "Plaintiffs have shown that Feldene can cause hepatitis." *Id.* The court noted, however, that some treating physicians and the defendant's expert witness believed that the decedent's illness was a type of hepatitis unrelated to medication. *Id.* Affirming judgment for the defendant, the court found that the plaintiffs offered no evidence excluding the possibility that the decedent had this type of hepatitis. *Id.* "In short, Plaintiffs did not offer sufficient evidence from which a reasonable jury could have concluded that Feldene was the most probable cause of Mrs. Gordon's hepatitis." *Id.*

[20] Pipitone v. Biomatrix, Inc., 288 F.3d 239, 243 n.5 (5th Cir. 2002) (citing Joseph v. Bohn Ford, Inc., 483 So.2d 934, 940 (La. 1986); Todd v. State, 699 So.2d 35, 43 (La. 1997)).

[21] *See Wheat*, 31 F.3d at 342–43.

[22] For an explanation of TAX 316, see this Court's order issued October 21, 2020 (Doc. 11332).

[23] Doc. 10926-3 at 48.

explains that she conducted the "Fisher's exact" test and that she "did the 2x2 table looking at whether the rate of persistent alopecia in patients who had been exposed to [TAC], as compared to the rate/percentage in patients [who] had been exposed to [FAC], and determined that that was not a statistically significant difference."[24] She further testified that "by doing that calculation is the only way I would have been able to state assertively that there is not a statistically significant difference between those two arms."[25] Based on this, the Court finds that Dr. Arrowsmith used a valid methodology to reach her opinion. Her opinion, therefore, is admissible. To the extent Plaintiff finds weaknesses in Dr. Arrowsmith's application of the methodology, Plaintiff can reveal this on cross-examination.

Plaintiff raises other challenges to Dr. Arrowsmith's TAX 316 opinions. Plaintiff argues that she improperly relies on the results of TAX 316 as interpreted by Dr. Michael Kopreski. For background on Dr. Kopreski's interpretation of TAX 316, see this Court's Order and Reasons dated October 21, 2020 (Doc. 11332) ("Order on Kopreski"). In response, Sanofi argues that Dr. Arrowsmith can reasonably rely on the work of others.

For the reasons provided in its Order on Kopreski, the Court rejects Plaintiff's assertion that Dr. Kopreski's work was litigation-driven and therefore unreliable and inadmissible. For the same reasons, the Court rejects the notion that Dr. Kopreski was not qualified to analyze the TAX 316 data. In addition, the Court rejects Plaintiff's argument that Dr. Arrowsmith made no attempt to independently validate Dr. Kopreski's work. To the contrary, Dr. Arrowsmith explained Dr. Kopreski's work in detail, and she examined patient data for two TAX 316 patients and reached the same conclusions as Dr.

[24] Doc. 11098-4 at 3.
[25] *Id.*

Kopreski, leading her to conclude his analysis was reliable. Dr. Arrowsmith, therefore, may consider and rely upon Dr. Kopreski's work.

II. Dr. Arrowsmith's Regulatory Opinions

Plaintiff argues that while Dr. Arrowsmith has the qualifications to offer regulatory opinions, she failed to properly disclose and explain these opinions. Specifically, Plaintiff first argues that Dr. Arrowsmith defines the term "reasonable evidence" without reference or support. Dr. Arrowsmith uses this phrase when she explains, quoting federal regulations, that "the Warnings and Precautions section of labeling 'must be' revised to include a warning about a 'clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug.'"[26] She then states that "[i]n this context, reasonable evidence of a causal association means a signal is confirmed and is not merely a 'weak' or 'potential' signal referred to further evaluation."[27]

The Court finds that Dr. Arrowsmith has support for this definition. In her report, she makes clear that using "medical and regulatory judgment" is sometimes necessary to define a term when statutory definitions are not available.[28] In her deposition testimony, she specifically clarifies that her definition of "reasonable evidence" is based on her knowledge of safety signals and how they are evaluated.[29] This knowledge stems from her years of regulatory experience. This definition, then, is supported and admissible.

Lastly, Plaintiff argues that Dr. Arrowsmith offers testimony that strays from the federal regulations at issue. Plaintiff avers that while Dr. Arrowsmith recognizes the standards that must be met to update a drug label, she applies the wrong standard. Specifically, Dr. Arrowsmith acknowledges that to update

[26] Doc. 10926-3 at 15.
[27] *Id.*
[28] *Id.*
[29] Doc. 11098-4 at 4.

the "Warnings and Precautions" section of a drug label, there must be "reasonable evidence of a causal association" between exposure to the drug and onset of the adverse clinical event.[30] Plaintiff would have the Court believe that, although Dr. Arrowsmith acknowledges this standard, she then opines that unequivocal causation is required before updating a drug label.

Plaintiff misrepresents Dr. Arrowsmith's report. Nowhere in her report does she state or imply that unequivocal causation is required before updating a drug label. Instead, it is in the "Epidemiology and Causation" section of her report, which is separate from the sections of her report that relate to drug labeling, that she writes that "the currently available scientific evidence does not support an unequivocal causal role for Taxotere alone in persistent or permanent alopecia."[31]

Elsewhere in her report, she offers a straightforward explanation of why, in her opinion, permanent alopecia was not appropriate in the "Warning and Precautions" section of the Taxotere label. She explains that this section is reserved for serious adverse events, and she opines that alopecia does not meet the definition of a serious adverse event.[32] This labeling opinion clearly rests on the seriousness of permanent alopecia, not on any causal standard. The Court, therefore, will not preclude this opinion based on Plaintiff's assertion that Dr. Arrowsmith applied the wrong causal standard.

Similarly, her opinion on the "Adverse Reactions" section of the Taxotere label does not rely on any causal standard. She opines only that the language warning of "alopecia" was sufficient to warn of permanent alopecia because alopecia does not mean "temporary hair loss."[33] In addition, she notes that

[30] Doc. 10926-3 at 18.
[31] *Id.* at 57.
[32] *Id.* at 32.
[33] *Id.* at 32–33.

"[t]here is no consensus definition by regulation for 'ongoing,' 'persistent,' 'permanent,' or 'irreversible' alopecia."[34] This opinion, then, is based on semantics, not causation. Ultimately, Dr. Arrowsmith does not provide any opinions that contradict the pertinent regulations as Plaintiff suggests. The Court, therefore, will not limit her opinions on this basis.

CONCLUSION

For the foregoing reasons, Plaintiff's Motion to Exclude Testimony of Dr. Janet Arrowsmith (Doc. 10926) is **DENIED**.

New Orleans, Louisiana, this 8th day of January, 2021.

JANE TRICHE MILAZZO
UNITED STATES DISTRICT JUDGE

[34] *Id.*